

REMARKS

With entry of this amendment, claims 1-94 and 96-143 are pending in the application. All of the pending claims are under examination on the merits. By this amendment, claims 10, 11, 47, 90, 115, 116, 118, 124, and 142 have been amended for clarity in accordance with the Office's suggestions. The subject amendments are fully supported by the specification and no new matter has been added to the application. Entry of this submission and reconsideration of the application is earnestly solicited.

Status of Application

Applicants note that the Office has entered Applicant's submission and Request for Continued Examination filed August 26, 2002, and has withdrawn the finality of the previous Office Action (Paper No. 22).

Status of File Wrapper

The Office cannot locate the original claims submitted on May 22, 1998, and has therefore requested has a replacement copy of the claims. A true copy of the originally filed claims is enclosed herewith.

Status of Record

Applicants acknowledge that certain issues raised in Applicant's response filed August 26, 2002, (at pages 4-6) regarding the previous Examiner's comments contained in previous Office Actions, as referenced in the instant Office Action (Paper No. 32, at p. 2), were either addressed and resolved during the personal interview on November 22, 2002 attended by Applicants' representative, Jeffrey King, Applicants Brian Murphy and Peter Collins, Primary examiner Park and examiner Brown, or have been obviated by further prosecution developments in the application.

Patentability Under 35 U.S.C. §§ 102 and 103

Based on the prosecution history of the application and in view of the present Office Action (Paper No. 32) Applicants believe that the Office has thoroughly considered the subject matter of the application and has concluded that the pending claims are free of the prior art. Accordingly, the Office has reconsidered and withdrawn the previous rejection of claims 91 and 92 under 35 U.S.C. 102(b) as allegedly anticipated by Dimock *et al* (*J. Virology*, 1993). In addition, the Office has

reconsidered and withdrawn the previous rejection of claims 1-4, 6, 7, 10-17, 20, 21, 26, 27, 30, 33-40, 43, 44, 47-49, 52, 54, 56, 57, 59, 61-85, 88-91, 93, 94, 96-116, 118 and 120-143 under 35 U.S.C. 102(e) as allegedly anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Belshe *et al* (5,869,036). Likewise, the Office has reconsidered and withdrawn the prior rejection of claims 51 and 53 under 35 U.S.C. 103(a) as allegedly obvious over Belshe *et al*. Similarly, the Office has reconsidered and withdrawn the previous rejection of claims 18, 19, 28 and 29 under 35 U.S.C. 102(e) as allegedly anticipated by Belshe *et al*, or in the alternative, under 35 U.S.C. 103(a) as allegedly obvious over Belshe *et al* in view of Stokes *et al* (*Virus Research*, 1993). Finally, the Office has reconsidered and withdrawn the rejection of claims 22-25, 31, 32, 42, 60, 117 and 119 under 35 U.S.C. 103(a) as allegedly obvious over Belshe *et al* in view of Conzelman (*J Gen. Vir.*, 1996).

Claim Objections

Claims 90 and 142 are objected to because of the following informalities: Claim 142, “genes of HPIV3 to for said infectious, chimeric particle” is unclear. In claim 90, line 1, “infectious” is misspelled. Appropriate corrections of the subject informalities in the claims are presented herein.

Patentability Under 35 U.S.C. §§ 112, First Paragraph

Applicants acknowledge that the Office has reconsidered and withdrawn the previous rejection of claims 15, 16, 30, 31, 36, 37, 39, 65-69, 71, 72, 78, 81, 82, 105, 106, 109-111, 113, 114, 117, 127, 128, 130, 131, 133, 135, 138 and 139 under 35 U.S.C. 112, first paragraph (relating to deposited material).

Applicants acknowledge that the Office has reconsidered and withdrawn the previous rejection of claims of claims 1-94 and 96-143 under 35 U.S.C. 112, first paragraph (scope of enablement).

Claims 47, 90, 115 and 116 are rejected under 35 U.S.C. 112, first paragraph for alleged non-enablement. The Office acknowledges that the specification is fully enabling for a composition that *induces an immune response* against PIV and/or RSV, but asserts that for *protective immunity* against PIV and/or RSV is lacking (Office Action Paper No. 32, at pp. 5-6).

Applicants respectfully traverse the stated grounds for rejection and submit that the disclosure is fully enabling for compositions that elicit protective immunity against RSV and PIV. In this context, it is not a requirement that the disclosure enable induction of a fully protective

immune response in all mammalian subjects, as evidently advocated by the Office. On the contrary; even if a vaccine composition is protective in some patients (e.g., infants) but not others (e.g., adults), the ineffectiveness in one group does not render a claim to a protective composition invalid.

Nonetheless, the foregoing rejection is obviated by the amendments herein to remove the allegedly objectionable term “protective” from the subject claims. The claims now recite more broadly the result of eliciting “an immune response” in a mammalian host, whereby it is rendered more clear that not all immune responses elicited by the claimed compositions and methods must elicit full protection in all subjects. On this basis, withdrawal of the rejection of claims 47, 90, 115 and 116 under 35 U.S.C. 112, first paragraph is earnestly solicited.

Patentability Under 35 U.S.C. §§ 112, Second Paragraph

Applicants acknowledge that the Office has reconsidered and withdrawn the prior rejection of claim 111 under 35 U.S.C. 112, second paragraph in view of Applicant's amendments.

Claims 10-47, 90, 115, 118-128, 133-134 and 142-143 are rejected under 35 U.S.C. 112, second paragraph, for alleged indefiniteness. The grounds for rejection specified by the Office are addressed below in the order presented.

Claim 10 is objected to for allegedly containing improper Markush language. Although the original Markush format is believed to comport with the statutory requirements, the subject term “or” has been replaced by the more standard Markush term –and--.

Claim 11 is considered to lack clarity in the recitation of “said polynucleotide” in line 5. The subject language has been clarified to recite “said isolated polynucleotide” which in turn is indicated by the language of the claim to comprise the “polynucleotide sequence encoding said PIV genome or antigenome”.

In claims 47, 90, 115 and 116, the Office considers that the term “capable of” is unclear, because it is not known whether or not the pathogen actually elicits a protective immune response. The subject claims have been amended to positively recite the indicated biological activity. In a related context, the Office states that in claims 47, 90 and 115 it is unclear which element is eliciting a protective immune response. The subject claims have been amended to refer specifically to a protein of a microbial pathogen and to specify that the protein elicits an immune response in a mammalian host “when the protein is incorporated in the isolated infectious PIV particle”.

The Office also considers claim 118 to be unclear in the recitation of an “immunogenically effective amount”. While this term is considered to sufficiently convey the metes and bounds of the invention in view of the disclosure, the subject claim has been amended to remove the allegedly objectionable term and thereby obviate the rejection.

Claim 124 is considered indefinite for lack of antecedent basis for the term “said infectious, chimeric PIV particle”. Appropriate correction is presented herein.

In light of the foregoing amendments and comments, withdrawal of the rejection of claims 10-47, 90, 115, 118-128, 133-134 and 142-143 under 35 U.S.C. 112, second paragraph is respectfully requested.

Double Patenting

Claims 1-94 and 96-143 are provisionally rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over:

- Claims 1-6, 8-45, 47-50 of copending Application 09/458,813,
- Claims 1-58 of copending Application 09/459,062, and
- Claims 1-94 and 96-128 of copending Application 09/424,628

Claims 1, 2, 5-10, 33-42, 73, 74, 76-80, 83, 88, 89, 97-99, 101-111, 122, 123 and 141 remain provisionally rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-83 of copending Application 09/586,479.

Applicants do not accede to the merits of the foregoing, obviousness-type double patenting rejections. However, the rejections are obviated and their merits rendered moot on the basis that Applicants have filed herewith a Terminal Disclaimer in the instant application over each of the applications noted above: U.S. Patent Application No.s 09/458,813, 09/459,062, 09/424,628, and 09/586,479. No representations are made by this submission with regard to the existence or non-existence of patentable differences between the subject matter disclosed and claimed in the instant application and the cited applications noted above.

In view of the foregoing, the double patenting rejections of claims 1-94 and 96-143 are believed to be overcome.

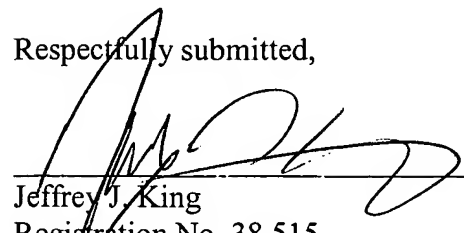
CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (425) 455-5575.

Respectfully submitted,

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